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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/634,656 | 08/05/2003 | Richard L. Dunn | 1195.323US1 | 6348 |
| 21186 7590 03/09/2009 SCHWEGMAN, LUNDBERG & WOESSNER, P.A. P.O. BOX 2938 MINNEAPOLIS, MN 55402 | | | EXAMINER MACNEILL, ELIZABETH | |
| | | | ART UNIT 3767 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/634,656

Applicant(s)

DUNN ET AL.

Examiner

ELIZABETH R. MACNEILL

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 3-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 3-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1, 3-8, 10, 11, and 13-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu (US 4,743,229) in view of Cardenas (US 5,616,133).

Chu teaches a first syringe (14) with integral male end portion (inner protrusion of 44) and locking ring (outer annulus of 44) spaced from the outer end surface of the male luer (Fig 1-3); a first syringe plunger (34); a second syringe with female luer (50) and exteriorly protruding members (54); a second syringe plunger (36); wherein the first and second syringes are coupled and the female luer fits between the locking ring and the male luer (Fig 3).

Chu does not teach that the female luer is integral with the second syringe.

Cardenas teaches a mixing syringe in the same field of endeavor (medicament mixing devices) which includes an integral female luer (Fig 2, Col 3 line 3, element 24).

Providing an integral luer reduces the number of parts of the device and makes it easier to control in the field (no dropping the connector, extra step of effectuating the connection). It would have been obvious to one of ordinary skill in the art at the time the invention was made to make female luer (50) of Chu integral with the second syringe since it is known in the art to provide integral luers on mixing syringes and it has been

held that improving similar devices in the same way is within the skill of an ordinary worker in the art.

Claims 3, 4: Cardenas teaches a male luer (Fig 11) connected to a needle assembly (28). The male luer of Chu is clearly capable of connection to the standard needle assembly shown in Cardenas.

Claims 15, 16, 23, and 24: CHu teaches mixing a generic medication and diluents but does not teach the specific drug and diluents claimed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use lyophilized leuprolide acetate with Poly (D,L-lactide-co-glycolide) (PLG) dissolved in a biocompatible solvent N-methyl 2-pyrrolidone as a simple substitution of one known device for another since it is well known in the art that leuprolide acetate is used to treat endometriosis.

3. Claims 9 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chu/Cardenas as applied to claims above, and further in view of Kanno (US 4,629,455). Chu/Cardenas does not teach a rotatable locking ring. Kanno teaches a rotatably coupled locking ring mounted on a medical instrument. It would have been obvious to one of ordinary skill in the art, at the time of invention to have modified the connecting structure of Chu/Cardenas with the connecting member as taught by Kanno for the well known purpose of providing a male and female connection alternative that can be joined firmly with high reliability.

Response to Arguments

4. Applicant's arguments with respect to claims 1 and 3-24 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

1. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Simmons/
Supervisory Patent Examiner, Art Unit 3767